DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 15, 2015

Back 2 Basics Direct, LLC
% Mr. Samuel Pollard
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street Northwest, 12th Floor
Washington, District of Columbia 20005

Re: K150184
Trade/Device Name: Dymaxeon Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: May 13, 2015
Received: May 14, 2015

Dear Mr. Pollard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150184

Device Name
Dymaxeon Spine System

Indications for Use *(Describe)*
The Dymaxeon Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1-S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Trade Name: Dymaxeon Spine System

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Date Prepared: May 13, 2015

Classification: 21 CFR 888.3070: Pedicle screw spinal system

Class: III

Product Code: NKB, MNI, MNH

Indications for Use:
The Dymaxeon Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Purpose of Submission:
The purpose of this 510(k) is to add additional rod, pedicle screw, transverse connectors, and hooks to the previously cleared Dymaxeon Spine System. Specifically, B2B Direct is adding a

Ø5.5 mm rod component option, a cannulated screw option to the currently marketed Ø6.0 mm rods and solid screws cleared in K121786, a transverse connector to increase torsional rigidity, and hook options (laminar, pedicular, and offset) to provide the surgeon with more support options. The transverse connector is available in non-axial and multi-axial configurations.

Device Description:
The Dymaxeon Spine System is a posterior pedicle screw system manufactured from titanium alloy (Ti6Al4V ELI per ASTM F136) designed for temporary stabilization of the spine during the development of spinal fusion. The Dymaxeon Spine System is comprised of polyaxial pedicle screws and rods. The Dymaxeon Spine System can be used for single or multiple level fixations.

The additional Ø5.5mm rod, cannulated screw, transverse connector, and hook components will be used in conjunction with the predicate Dymaxeon Spine System during the fixation of the spine. The components are manufactured from titanium alloy and come in a variety of lengths.

No other modifications have been made to the Dymaxeon Spine System.

Predicate Devices:
The Ø5.5mm rod, cannulated screw, and transverse connector components are substantially equivalent to the primary predicate Dymaxeon Spine System (K121786). Additional predicate devices include the Corelink Tiger Spine System (K113058), the Blackstone SFS Parallel Rod Connectors (K080407), the Synthes Anterior CSLP System (K000536), and the Stryker Xia Spinal System (K071373).

Technological Characteristics:
The Ø5.5mm rod, cannulated screw, and transverse connector components are substantially equivalent to the referenced predicates with respect to its intended use, material, geometry, and method of fixation.

Preclinical Testing:
The non-clinical tests performed by the company include static compression bending, static torsion, and dynamic compression bending testing per ASTM F1717 of the Ø5.5mm rod and cannulated screw components. The results of the performed tests demonstrate that the Dymaxeon Spine System with Ø5.5mm rod, cannulated screw, and transverse connector components is substantially equivalent to legally marketed predicate devices.

Conclusion:
The information summarized in the Design Control Activities Summary demonstrates that the Ø5.5mm rod, cannulated screw, transverse connectors, and hooks are substantially equivalent to the predicate device as demonstrated by mechanical testing.